

REMARKS

Claims 1, 2, 13, 14, 17-32, 34, 35, 41, 64, 65, 68-80, and 82-86 are pending in this application and are currently under examination. No new matter is added.

Rejections Based Upon the Scaria Publication

All but two of the pending claims stand rejected in view of US 2003/0229036 (“the Scaria publication”). Claims 1, 2, 13-25, 29-32, 34, 35, and 41 stand rejected under 35 U.S.C. § 103 as allegedly being obvious in view of the Scaria publication and the teachings of two U.S. patents, and claims 1, 2, 13-23, 29-32, 34, 35, 41, 64-73, 78-80, and 82-84 stand rejected on the ground of nonstatutory obviousness-type double patenting in view of the Scaria publication and the claims of yet another U.S. patent. Applicants request that the basis for these rejections be established or that they be withdrawn.

As Applicants noted in prior correspondence, because the Scaria publication qualifies as prior art, if at all, under Section 102(e), the Examiner is required to indicate whether or not he is of the view that an interference should be declared between the instant claims and the claims pending in the patent application underlying the Scaria publication:

If there is no common assignee or inventor and the rejection under 35 U.S.C. 102(e) is the only possible rejection, the examiner must determine whether an interference should be declared.

(M.P.E.P. 706.02(b), emphasis added). The reason for requiring this determination, as stated in the M.P.E.P., is that it dictates the manner in which an applicant may respond:

When the claims of the reference U.S. patent or U.S. patent application publication and the application are directed to the same invention or are obvious variants, an affidavit or declaration under 37 CFR 1.131 is not an acceptable method of overcoming the rejection.

(*Id.*). In spite of these substantive considerations, and in spite of Applicants’ prior requests, the Office Action fails to indicate whether or not the Examiner is of the view that an interference should be declared between the instant claims and those pending in the application corresponding to the Scaria publication. Applicants respectfully request that this

determination be made, or that the rejections based upon the Scaria publication be withdrawn.¹

Rejection Based on Other Publications

Claims 85 and 86 have been rejected under 35 U.S.C § 103(a) as allegedly being obvious in view of WO 98/38317, corresponding to US Patent No. 6,573,071 (“the Himmelspace publication”) and U.S. Patent No. 5,288,629 (“the Berkner patent”). The apparent basis for this rejection is that the Himmelspace publication teaches an expression system including a nucleic acid encoding a Factor X analog with a modified cleavage site, and that it allegedly would have been obvious to a person of ordinary skill in the art to modify this expression system to include a nucleic acid expressing Factor VII or Factor IX, in place of the nucleic acid expressing Factor X, because Factor VII and Factor IX were also known in the art (as demonstrated by the Berkner patent). (Office Action, page 9). Applicants respectfully request reconsideration of this rejection because there is no reason to believe that a person of ordinary skill having knowledge of the cited references (but not Applicants’ disclosure) would have combined the references’ respective teachings, much less that they would have combined them in the manner proposed.

Obviousness cannot be established based on a combination of references absent “a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *Takeda Chem. Indus. Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356-57 (Fed. Cir. 2007) (citing *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1731 (2007)). See also May 3, 2007 Memo from Margaret A. Focarino, Deputy Commissioner for Patent Operations, U.S. Patent Office (“it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed.”) (commenting on *KSR Int’l Co.*, 127 S. Ct. 1727 (2007)).

Tellingly, however, the Office Action fails to identify any reason why a person of ordinary skill who did not already have knowledge of Applicants’ inventions would have attempted to combine the teachings of the Himmelspace publication and the Berkner patent.

¹ Applicants note that on June 25, 2009, a Notice of Allowance issued in the patent application corresponding to the Scaria application, *i.e.*, US Application No. 10/057,620.

The Office Action asserts that those of ordinary skill would have been motivated to do so “to increase the stability of [Factor VII and Factor IX] in a cell” (Office Action, page 9), but does not identify any evidence indicating those of ordinary skill would have recognized the type of cleavage site modification disclosed in the Himmelspach publication as a way to enhance the stability of Factor VII or Factor IX in a cell. The Himmelspach publication, for example, refers to shelf stability of a Factor X preparation “in dissolved form” (US Patent No. 6,573,071 at col. 11, lines 52-56),² but does not appear to refer to stability of Factor X in a cell. Absent evidence indicating that those of ordinary skill would have been motivated by stability in a cell to modify the cited references in the manner that the Office Action suggests, the rejection for alleged obviousness is improper and should be withdrawn.

Conclusion

Applicants believe that the foregoing constitutes a complete and full response to the Office Action of record. Accordingly, an early and favorable Action is respectfully requested. Should any issues remain unresolved by the present remarks, the Examiner is invited to contact the undersigned at 215.568.3100.

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² “The preparation according to the present invention is particularly stable, i.e. it can be left standing in dissolved form over an extended period of time before application. The preparation according to the invention has proven to show no loss in activity for several hours up to days.”